I. REMARKS

A. Amendments

Applicants note that the Office Action Summary reflects that Claims 1-37 are pending in the instant application. However, on September 14, 2004, Applicants filed a Preliminary Amendment adding new Claims 38-46. A copy of the Preliminary Amendment is attached in Appendix A.

B. Election of Coating Process

The Examiner has also requested that Applicants elect between the coating processes of "dipping" and "spraying". As indicated above, Applicants have deleted the claims directed to specific coating processes, including dipping and spraying. Applicants according request that the election request relating to the coating processes be withdrawn.

If the Examiner has any further questions or wishes to address any other matter,
Applicants invite the Examiner to call Applicants' attorney at the number given below to
advance the prosecution of this matter

Respectfully submitted,

FRANCIS LAW GROUP

By

Ralph C. Francis

Reg. No. 38,884

Dated: March 7, 2005 1942 Embarcadero Oakland, CA 94606 (510) 533-1100

I hereby certify that this document is being deposited with the United States Postal Service on this date 3-7-05 as "First Class Mail" in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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APPENDIX A

MESSAGE CONFIRMATION



SEP-14-2004 04:26 PM TUE

FAX NUMBER : 650 564 2195

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NAME/NUMBER : 817038729306

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RESULTS

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Under the Paperwork Roduction Act of 1995, n	Application Number	ollection of information unless it displays a valid OMB control number. 10/045,842
TRANSMITTAL	Filing Date	October 26, 2001
FORM	First Named Inventor	Michel J.N. Cormier
(to be used for all currespondence after initial filir	gi Art Unit	3763
	Examiner Name	Unassigned
Total Number of Pagos in This Submission	19 Attorney Docket Number	ARC 3036 R1
	ENCLOSURES (Check a	ll that apply)
Fee Transmittal Form	Drawing(s)	After Allowance Communication to Technology Conter (TC)
Fee Attached	Licensing-related Papers	Appeal Communication to Board of Appeals and Interferences Appeal Communication to TC
Amendment/Roply	Petition Petition to Convert to a	(Appeal Notice, Brief, Reply Brief)
After Final	Provisional Application	Proprietary Information
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Extension of Time Request	Terminal Disclatmer	Other Enchaure(s) (please Identify below):
T	Request for Refund	Preliminary Amendment; Amendment, Request and
Express Abandonment Request		Fee to Add Inventor, Declaration and Power of Attorney, Declarations of Inventors, and Consent to
Information Disclosure Statement	CD, Number of CD(s)	Add inventor
Certified Copy of Priority Document(s)	Remarks	
Response to Missing Parts/ Incomplete Application		
Response to Missing Parts under 37 CFR 1.52 or 1.53		
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I hereby certify that this correspondence is be sufficient peetings as first class mail in an en- the date shown below.	rdopo addressed to: Commissione	PTO or deposited with the thrited States Postal Service with for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on
	(7	03) 872-9306
Typed or printed name Susan Aheam	n	
Signature	allean	Date G/W/OU

This collection of Information is required by 37 CFR 1.5. The information is required to obtain or rotain a benefit by the public which is to the (and by the USPTO to process) an application. Confidentiality is governed by \$5 U.S.C. 122 and \$7 CFR 1.1.4. This collection is estimated to taxe 2 hours to complete, including gathering, preparing, and submitting the completed application from to the USPTO. Time will very dependent open the individual case. Any commands on the amount of time you require to complete this form and/or auggestions for rortucing this burden, should be sent to the Chief Information Officer, U.S. Petant and Tracement Office, U.S. Department of Commonce, PO. Os. 1450, Assandins, VA 22131-1450. OD NOT SERIO FIEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commission set for Patients, PO. De so 1450, A leasandins, VA 22131-1450.

PRELIMINARY AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

DOCKET NO: ARC 3036 R1

Dear Sir:

The following amendments and remarks are provided before the initial examination of the above-identified patent application. Examination and consideration of the above application in light of the following amendments and remarks is respectfully requested.

Please amend the application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims, which begins on page 4 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Attorney Docket: ARC 3036 R1
Preliminary Amendment

I. AMENDMENTS

Amendments to the Specification:

Please add the following new paragraph and heading before paragraph [0001]:

-- CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/244,038, filed October 26, 2000.--

Please replace paragraph [0001] with the following amended paragraph:

[0001] [0001.1] This invention relates to administering and enhancing transdermal delivery of an agent across the skin. More particularly, the invention relates to a percutaneous drug delivery system for administering a potent pharmacologically active agent through the stratum corneum using skin piercing microprotrusions which have a dry coating of the pharmacologically active agent. Delivery of the agent is facilitated when the microprotrusions pierce the skin of a patient and the patient's interstitial fluid contacts and dissolves the active agent.

Please replace paragraph [0028] with the following amended paragraph:

[0028] FIG. 8 is a graph showing the amount of human-growth hormone desmopressin delivered by a microprotrusion array that has been tip-coated as described in Example 2B.

Please replace paragraph [0030] with the following amended paragraph:

[0030] FIG.10 is a graph showing the amount <u>delivery efficiency</u> of ovalbumin delivered administered by a microprotrusion array that has been tip-coated as described in Example 6B.

Please replace paragraph [0066] with the following amended paragraph:

Attorney Docket: ARC 3036 R1 Preliminary Amendment

[0066] Studies were performed in hairless guinea pigs to evaluate the kinetics of drug absorption through the skin from hGH tip-coated microprotrusion array systems. System application was performed on the flank of the anesthetized animals with an impact applicator delivering an energy of 0.26 J in less than 10 milliseconds. The system applied comprised a coated microprotrusion array device, adhered to the center of a LDPE backing with an adhesive (7 cm² disc). Systems remained on the skin for 5 seconds (n=3) or 5 minutes (n=5). A group of animals (n=5) received a subcutaneous injection of 10 µg hGH. Blood samples were collected at time intervals for plasma hGH determination by ELISA. The hGH dose delivered was extrapolated based on an area under the curve (AUC) calculation compared to IV administration of hGH. Results showed that hGH delivery from the microprotrusion array was the same with 5 seconds (open triangles) and 5 minutes (close circle) wearing times (FIG. 9). On average, 5 [[82 g]] µg of hGH was delivered in each animal, which accounts for approximately 50% of the coated dose. This is to compare with a bioavailability of 65% following subcutaneous administration of hGH, the results of which are shown as "X" (FIG.9).

Attorney Docket: ARC 3036 R1 Preliminary Amendment

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 38. (New) A method of transdermally delivering a pharmacologically active agent to a patient, comprising the steps of:

providing a microprotrusion member having a plurality of stratum corneum-piercing microprotrusions, said microprotrusion member having a coating disposed thereon, said coating including at least one pharmacologically active agent, said pharmacologically active agent being sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg; and

applying said microprotrusion member to a skin site on the patient, whereby said plurality of stratum corneum-piercing microprotrusions pierce the stratum corneum and deliver said pharmacologically active agent to the patient,

wherein said delivered pharmacologically active agent has improved pharmacokinetics compared to pharmacokinetics after subcutaneous injection.

Claim 39. (New) The method of Claim 46, wherein said pharmacologically active agent is selected from the group consisting of ACTH(1-24), calcitonin, desmopressin, LHRH, LHRH analogs, goserelin, leuprolide, PTH, vasopressin, deamino[Val4, D-Arg8) arginine vasopressin, buserelin, triptorelin, interferon alpha, interferon beta, interferon gamma, FSH, EPO, GM-CSF, G-CSF, IL-10, glucagon, growth hormone releasing factor (GRF), and analogs and pharmaceutically acceptable salts thereof.

Claim 40. (New) The method of Claim 38, wherein said improved pharmacokinetics comprises increased bioavailability of said pharmacologically active agent.

Claim 41. (New) The method of Claim 38, wherein said improved pharmacokinetics comprises an increase in C_{max} .

Claim 42. (New) The method of Claim 38, wherein said improved pharmacokinetics comprises a decrease in T_{max} .

Claim 43. (New) The method of Claim 38, wherein said improved pharmacokinetics comprises an enhanced absorption rate of said pharmacologically active agent.

Attorney Docket: ARC 3036 R1 Preliminary Amendment

Claim 44. (New) The method of Claim 38, wherein said coating is formed from an aqueous solution having solubility greater than approximately 50 mg/ml.

Claim 45. (New) The method of Claim 44, wherein said aqueous solution has a viscosity less than approximately 500 centipoises.

Claim 46. (New) The method of Claim 38, wherein each of said plurality of stratum corneum-piercing microprotrusions has a length less than approximately 500 microns.

Attorney Docket: ARC 3036 R1
Preliminary Amendment

REMARKS

The foregoing amendments are made in order to place the Application in better condition for examination and to better define the invention. As no new matter is presented with these amendments, it is believed that such amendments may be entered and such action is respectively requested.

Respectfully submitted, FRANCIS LAW GROUP

By

Ralph C. Francis Reg. No. 38,884

Dated: August 18, 2004 1808 Santa Clara Ave Alameda, CA 94501 (510) 769-9800